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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/502,078 | 07/19/2004 | Patrick Wuthrich | SERVIER 426 PCT | 2097 |

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THE FIRM OF HUESCHEN AND SAGE
SEVENTH FLOOR, KALAMAZOO BUILDING
107 WEST MICHIGAN AVENUE
KALAMAZOO, MI 49007

| EXAMINER | |
|---|---|
| TRAN, SUSAN T | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

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| 01/06/2010 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/502,078 | WUTHRICH ET AL. | |
| | Examiner | Art Unit | |
| | S. Tran | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *12-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-16 and 19-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 7,201,922 ('922). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '922 patent recites a compressed orodispersible solid pharmaceutical composition in a solid dosage form having a hardness of between 30 and 300 Newtons, comprising: spherical granules consisting essentially of co-spray-dried lactose and granular starch; at least one pharmaceutically active substance, wherein said composition disintegrates in the mouth in less than one minute, and wherein the said granules represent 20% to 99% by weight

of said solid dosage form. The '922 patent does not specific recite the claimed active agent such as piribedil. However, it would have been obvious to one of ordinary skill in the art to optimize the solid dosage form of the '922 patent to include piribedil. This is because the '922 patent teaches an orodispersible solid formulation useful for a wide variety of active agents including central nervous system regulators, vasculoprotective, or the like (claim 4).

Claims 12-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-22 of copending Application No. 10/502479 ('479) in view of US 20050049196 ('196). The claims of the copending application '479 recites a solid orodispersible pharmaceutical composition comprising: granules consisting of co-spray-dried lactose and starch; and perindopril or pharmaceutically acceptable salt thereof. The composition disintegrates in the mouth in less than three minute (claim 12). The process is found in claims 21 and 22. The claims of the copending application '479 do not recite the claimed active agent. However, perindopril and piribedil are known for the same treatment, such as Parkinson's disease (see paragraph 0040 of US '196). Thus, it would have been obvious to one of ordinary skill in the art to modify the orodispersible composition of the copending application using piribedil as an active agent.

This is a provisional obviousness-type double patenting rejection.

***Response to Arguments***

Applicant argues that the Office acknowledges that the solid orodispersible composition disclosed differs from that claimed for describing a distinct active agent. As

the different active agents exhibit distinct pharmacological activity, as well as side-effect and interaction profiles, it is submitted that the respective teachings are distinct in their own right and that one of ordinary skill in the art may not be expected to rely with any degree of certainty on such prior teaching in optimizing a formulation as described and claimed in the instant application. Reconsideration and withdrawal of such non-statutory obviousness-type double patenting rejections in view of the cited art are respectfully solicited.

However, in response to applicant's arguments with respect to the obviousness double patenting rejections, although the active agents are distinct between the claimed invention and the copending applications, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select active agents that would benefit from the co-spray dry lactose/starch and/or the orodispersible composition. Accordingly, the rejections are maintained.

***Claim Rejections - 35 USC § 103***

Claims 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. US 6,316,027, in view of Gereg US 2002/0039603.

This rejection has been withdrawn in view of applicant's Remarks.

Claims 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. US 6,316,027, in view of Luhn US 6,770,368.

Johnson teaches an oral solid unitary fast dissolving dosage forms for dopamine agonist comprising piribedil as an active agent, and carrier including lactose (abstract; column 5, lines 52-55; and column 6, lines 21-23). The dosage form further comprise additives such as flavoring agents, antioxidants, viscosity enhancers, coloring agents, flavoring agents, and citric acid (column 6, lines 42-53; claims 9 and 15). The dosage form has a disintegration time within 1-60 seconds when placed in the oral cavity (column 6, lines 5-8). Johnson further teaches a method for treating Parkinson's disease comprises orally administering to a patient the fast dissolving solid unitary dosage form comprising piribedil (column 5, lines 48-55; and claims 1-8). The process for preparing the dosage form is disclosed in column 5, lines 26-39; and examples.

Johnson does not explicitly teach the lactose is co-dried with starch.

Luhn teaches a composition of granules comprising co-dried lactose and starch useful as a carrier in pharmaceutical art (abstract; column 1, lines 7-9; column 2, lines 30-48; and column 5, lines 1-4). The granules can be compressed into tablet having hardness of at least 22 N and disintegration time within 60 minutes (example 2, and table at column 6). Thus, it would have been obvious to one of ordinary skill in the art to modify the fast dissolving dosage form of Johnson to include the co-dried lactose-starch in view of the teaching of Luhn to obtain the claimed invention. This is because Johnson teaches the desirability of using water dispersible carrier such as lactose. This is because Luhn teaches co-spray-dry lactose with starch to overcome the disadvantages of tableting using lactose alone, and because Luhn teaches a superior pharmaceutical carrier composes of co-spray-dry lactose and starch that exhibits

satisfactory disintegrating properties, reduced friability, efficient flow, and sufficient hardness while being only slightly hydroscopic.

***Response to Arguments***

Upon reconsideration, the rejection over Johnson et al. in view of Luhn is reinstated for the following reasons:

Applicant's Remarks filed 09/17/08 stated that:

> "With the instant response, the applicant invokes the provisions of the CREATE Act of 2004, disqualifying the cited Luhn art under 35 USC § 103(c). The applicant submits that the "claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made." See 35 USC § 103(c)(2)(A). With the instant response, the applicant amends the Specification to disclose that "The instant invention was made by or on behalf of parties to a joint research agreement which came into effect 21 December 2001 between LES LABORATOIRES SERVIER and ROQUETTE FRERES", in accord with 37 CFR § 1.71(g)(1). The applicant submits the appropriate processing fee set forth in 37 CFR § 1.17(i), herewith. Moreover, the applicant affirms under 37 CFR § 1.104(c)(4) the foregoing fact that the instant invention was made by or on behalf of parties to a joint research agreement within the meaning of 35 USC § 103(c), that such agreement was in effect on or before the date the claimed invention was made in accord with 37 CFR § 1.104(c)(4)(i)(A), and that the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement in accord with 37 CFR § 1o104(c)(4)(i)(B). As a result, the applicant solicits the disqualification of the cited Luhn art under 35 USC § 103(c), and thereby destroying the basis for the combination rejection in view of Johnson, et al."

However, this Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act) (Public Law 108-453; 118 Stat. 3596 (2004)), which was enacted on December 10, 2004 is effective for patents granted *on or after* December 10, 2004. It is of note that Luhn is granted and published on August 03, 2004, which is *before* December 10, 2004. Accordingly, the rejection over Luhn is maintained.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615